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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/995,007	11/26/2001	Nancy Carrasco	96700/708	9968

7590

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EXAMINER

HASHEMI, SHAR S

ART UNIT

PAPER NUMBER

1637

DATE MAILED: 03/12/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/995,007

Applicant(s)

CARRASCO ET AL.

Examiner

Shar Hashemi

Art Unit

1637

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 21 May 2002.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 56-75 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 56-75 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 28 January 2002 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☒ Other: *STIC report, Notice to Comply*.

## **DETAILED ACTION**

### ***Response to Amendment***

1. Applicant's amendment, filed on April 29, 2002 (Paper No. 5) is acknowledged.

Claims 1-55 have been cancelled.

New claims 56-75 have been added.

*Claims 56-75 are pending and being acted upon presently.*

### ***Drawings***

2. The drawings are objected to under 37 CFR 1.83(a) because in Figure 2, they fail to label the sequences with SEQ. ID. NO. identifiers as described in the specification. Any structural detail that is essential for a proper understanding of the disclosed invention should be shown in the drawing. MPEP § 608.02(d). A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

### ***Specification***

3. The use of the trademark "Applied Biosystems" (page 11, lines 28-29) has been noted in this application. Trademarks should be capitalized wherever they appear and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

4. The disclosure is objected to because of the following informalities: The Accession No. on page 20, line 24 is missing. The specification must be amended to incorporate an appropriate Accession No. Appropriate correction is required.

5. This application contains sequence disclosures (see Figure 2) that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth below or on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures. Sequence disclosures must have SEQ ID NO identifiers.

APPLICANT IS GIVEN THE RESPONSE PERIOD SET FORTH IN THIS OFFICE ACTION IN WHICH COMPLY WITH THE SEQUENCE RULES, 37 CFR 1.821 – 1.825. Failure to comply with these requirements will result in ABANDONMENT of the application under 37 CFR 1.821(g). Extensions of time may be obtained by filing petition accompanied by the extension fee under the provisions of 37 CFR 1.136. In no case may an applicant extend the period for response beyond the six month statutory period. Applicant is requested to return a copy of the attached Notice to Comply with the response. The application is not in compliance

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for the reason(s) set forth on the attached Notice to Comply With the Sequence Rules or CRF Diskette Problem Report.

*Claim Rejections - 35 USC § 112*

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 56-75 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A) Claims 56-62 are rendered indefinite because the detecting step in claim 56 is confusing. It is unclear as to how the expression of the mammalian sodium/iodide symporter is detected. Amending the claims to incorporate a detecting step would obviate the rejection.

B) Claims 63-70 are rendered indefinite because the detecting step in claim 63 is vague. It is unclear as to how the binding of the antibody to mammalian sodium/iodide symporter is quantified or determined. Amending the claims to incorporate a detecting step would obviate the rejection.

C) Claims 71-75 are rendered indefinite because the detecting step in claim 71 is vague. It is unclear as to how hybridization is detected in recited method of identifying an iodide transport protein from non-thyroid tissue. Amending the claims to further develop the detecting step would obviate the rejection.

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D) The phrase "Figure 2 (SEQ ID NO:1) renders claim 56 indefinite. It is unclear as to whether Figure 2 encompasses all or a portion of SEQ ID NO:1. Amending the claim to incorporate the nexus between Figure 2 and SEQ ID NO:1.

### SUMMARY

8. No claims are allowed. Claims 56-75 are free of the prior art but rejected under 112 2<sup>nd</sup> paragraph. The closest prior art is Vilijin, F et al, "Expression of the Thyroid Sodium/Iodide Symporter in *Xenopus laevis* Oocytes," The Journal of Biological Chemistry, Vol. 264, No. 20, July 15 1989, pp. 11901-11903 and Bonaldo, MF et al, "Normalization and subtraction: two approaches to facilitate gene discovery," Genome Research, 1996, Vol. 6, pp. 791-806. Vilijin et al provided initial data on the properties of sodium iodide symporter and its cognate mRNA by expressing it in *Xenopus laevis* oocytes and identifying the size of the mRNA that encodes the carrier protein. Vilijan do not teach or suggest a method of detecting expression of a mammalian sodium/iodide symporter in a mammalian tissue utilizing labeled antibodies or nucleic acid probes which can hybridize to SEQ ID NO: 1. Bonaldo et al teach four methods to generate normalize cDNA libraries from human, mouse, and rat. Bonaldo et al also teach a 507 bp sequence having 16.8% homology with SEQ ID NO: 1 (See Figure A of STIC Report). Bonaldo et al does not teach a 2839 bp sequence which shares a region of homology with the nucleic acid probe used in the method of detecting expression of a mammalian sodium/iodide transporter.

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### CONCLUSION

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shar Hashemi whose telephone number is (703) 305-4840 and whose e-mail address is shar.hashemi@uspto.gov. However, the Office cannot guarantee security through the e-mail system nor should official papers be transmitted through this route. The examiner is on flex-time schedule and can be best reached on weekdays from 7:00 a.m. to 3:30 p.m. If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Gary Benzion, can be reached on (703) 308-1119.

Any inquiry of a general nature, matching or filed papers or relating to the status of this application or proceeding should be directed to the Tracey Johnson for Art Unit 1637 whose telephone number is (703) 305-2982.

Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Center numbers for Group 1600 are Voice (703) 308-1235 and Before Final FAX (703) 872-9306 or After Final FAX (703) 308-9307.

**GARY BENZION, PH.D**  
**SUPERVISORY PATENT EXAMINER**  
**TECHNOLOGY CENTER 1600**

March 6, 2003

